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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,812	02/25/2002	James W. Simpkins	1540/144	2471

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BROMBERG & SUNSTEIN LLP  
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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT PAPER NUMBER

1614

DATE MAILED: 04/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**10/082,812**

Applicant(s)  
**Simpkins et al.**

Examiner  
**Kevin E. Weddington**

Art Unit  
**1614**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 27, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 23-26 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of: 0
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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CLAIMS 23-26 ARE PRESENTED FOR EXAMINATION.

APPLICANTS' AMENDMENT AND INFORMATION DISCLOSE STATEMENT FILED JANUARY 27, 2003 HAVE BEEN RECEIVED AND ENTERED. ACCORDINGLY, THE REJECTION MADE UNDER STATUTORY TYPE (35 U.S.C. 101) DOUBLE PATENTING AS SET FORTH IN THE PREVIOUS OFFICE ACTION AT PAGES 2 AND 3 IS HEREBY WITHDRAWN.

***DOUBLE PATENTING***

CLAIMS 23-26 ARE REJECTED UNDER THE JUDICIALLY CREATED DOCTRINE OF OBVIOUSNESS-TYPE DOUBLE PATENTING AS BEING UNPATENTABLE OVER CLAIMS 1-6 OF U.S. PATENT No. 5,843,934. ALTHOUGH THE CONFLICTING CLAIMS ARE NOT IDENTICAL, THEY ARE NOT PATENTABLY DISTINCT FROM EACH OTHER BECAUSE THE PRESENT APPLICATION TEACHES A METHOD FOR MITIGATING THE EFFECTS OF A FUTURE ISCHEMIC EVENT IN A SUBJECT WITH THE ADMINISTRATION OF A PROPHYLACTIC AMOUNT OF A NON-SEX HORMONE, AND THE PATENTED APPLICATION TEACHES A METHOD FOR CONFERRING A CYTOPROTECTIVE EFFECT ON A POPULATION OF CELLS IN A MALE OR FEMALE WITH AN ESTROGEN COMPOUND. CLEARLY, ONE SKILLED IN THE ART WOULD HAVE ASSUME THE PATENTED APPLICATION'S METHOD IS A PROPHYLACTIC TREATMENT AGAINST ISCHEMIA (PRESENT OR FUTURE) SINCE THE ESTROGEN COMPOUND IS USED AS A CYTOPROTECTIVE AGENT, THEN TO USE THE SAME ESTROGEN COMPOUND (NON-SEX HORMONE) TO PREVENT FUTURE ISCHEMIC EVENT IS OBVIOUS IN THE ABSENCE OF EVIDENCE TO THE CONTRARY.

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CLAIM 23-26 ARE NOT ALLOWED.

THE NONSTATUTORY DOUBLE PATENTING REJECTION IS BASED ON A JUDICIALLY CREATED DOCTRINE GROUNDED IN PUBLIC POLICY (A POLICY REFLECTED IN THE STATUTE) SO AS TO PREVENT THE UNJUSTIFIED OR IMPROPER TIMEWISE EXTENSION OF THE "RIGHT TO EXCLUDE" GRANTED BY A PATENT AND TO PREVENT POSSIBLE HARASSMENT BY MULTIPLE ASSIGNEES. SEE *IN RE GOODMAN*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *IN RE LONGI*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *IN RE VAN ORNUM*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *IN RE VOGEL*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); AND, *IN RE THORINGTON*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A TIMELY FILED TERMINAL DISCLAIMER IN COMPLIANCE WITH 37 CFR 1.321© MAY BE USED TO OVERCOME AN ACTUAL OR PROVISIONAL REJECTION BASED ON A NONSTATUTORY DOUBLE PATENTING GROUND PROVIDED THE CONFLICTING APPLICATION OR PATENT IS SHOWN TO BE COMMONLY OWNED WITH THIS APPLICATION. SEE 37 CFR 1.130(B).

EFFECTIVE JANUARY 1, 1994, A REGISTERED ATTORNEY OR AGENT OF RECORD MAY SIGN A TERMINAL DISCLAIMER. A TERMINAL DISCLAIMER SIGNED BY THE ASSIGNEE MUST FULLY COMPLY WITH 37 CFR 3.73(B).

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***DOUBLE PATENTING***

CLAIMS 23 IS REJECTED UNDER THE JUDICIALLY CREATED DOCTRINE OF OBVIOUSNESS-TYPE DOUBLE PATENTING AS BEING UNPATENTABLE OVER CLAIMS 1-22 OF U.S. PATENT No. 6,350,739. ALTHOUGH THE CONFLICTING CLAIMS ARE NOT IDENTICAL, THEY ARE NOT PATENTABLY DISTINCT FROM EACH OTHER BECAUSE THE PRESENT APPLICATION TEACHES A METHOD FOR MITIGATING THE EFFECTS OF A FUTURE ISCHEMIC EVENT IN A SUBJECT WITH A NON-SEX HORMONE, AND THE PATENTED APPLICATION TEACHES METHODS FOR CONFERRING PROTECTION ON A POPULATION OF CELLS ASSOCIATED WITH ISCHEMIA IN A SUBJECT WITH ENT-17 $\beta$ -ESTRADIOL (A NON-SEX HORMONE). AGAIN, ONE SKILLED IN THE ART WOULD HAVE ASSUME THAT THE PATENTED APPLICATION'S METHOD IS A PROPHYLACTIC TREATMENT AGAINST ISCHEMIA (PRESENT OR FUTURE) SINCE THE ACTIVE INGREDIENT (ENT-17 $\beta$ -ESTRADIOL) IS USED AS A CYTOPROTECTIVE AGENT, THEN TO USE THE SAME ACTIVE INGREDIENT TO PREVENT FUTURE ISCHEMIC EVENTS IS OBVIOUS IN THE ABSENCE OF EVIDENCE TO THE CONTRARY.

CLAIM 23 IS NOT ALLOWED.

THE NONSTATUTORY DOUBLE PATENTING REJECTION IS BASED ON A JUDICIALLY CREATED DOCTRINE GROUNDED IN PUBLIC POLICY (A POLICY REFLECTED IN THE STATUTE) SO AS TO PREVENT THE UNJUSTIFIED OR IMPROPER TIMEWISE EXTENSION OF THE "RIGHT TO EXCLUDE" GRANTED BY A PATENT AND TO PREVENT POSSIBLE HARASSMENT BY MULTIPLE ASSIGNEES. SEE *IN RE GOODMAN*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *IN RE LONGI*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *IN RE*

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*VAN ORNUM*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *IN RE VOGEL*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); AND, *IN RE THORINGTON*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A TIMELY FILED TERMINAL DISCLAIMER IN COMPLIANCE WITH 37 CFR 1.321 © MAY BE USED TO OVERCOME AN ACTUAL OR PROVISIONAL REJECTION BASED ON A NONSTATUTORY DOUBLE PATENTING GROUND PROVIDED THE CONFLICTING APPLICATION OR PATENT IS SHOWN TO BE COMMONLY OWNED WITH THIS APPLICATION. SEE 37 CFR 1.130(B).

EFFECTIVE JANUARY 1, 1994, A REGISTERED ATTORNEY OR AGENT OF RECORD MAY SIGN A TERMINAL DISCLAIMER. A TERMINAL DISCLAIMER SIGNED BY THE ASSIGNEE MUST FULLY COMPLY WITH 37 CFR 3.73(B).

#### **CONCLUSION**


APPLICANT'S AMENDMENT NECESSITATED THE NEW GROUND(S) OF REJECTION PRESENTED IN THIS OFFICE ACTION. ACCORDINGLY, **THIS ACTION IS MADE FINAL**. SEE MPEP § 706.07(A). APPLICANT IS REMINDED OF THE EXTENSION OF TIME POLICY AS SET FORTH IN 37 CFR 1.136(A).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH

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SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(A) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT, HOWEVER, WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO EXAMINER K. WEDDINGTON WHOSE TELEPHONE NUMBER IS (703) 308-1235.

  
Kevin E. Weddington  
Primary Examiner  
Art Unit 1614

K. WEDDINGTON

APRIL 14, 2003